



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: DP463707; **EPA FILE SYMBOL No.:** 70506-ANT; **PRODUCT NAME:** Shenzi SC Insecticide; **DECISION No.:** 577860; **ACTION CODE:** R310; **FOOD Use:** Yes; **COMPANY:** UPL NA Inc.
e-Submission#: 66572 / **Submission#:** 1073703

DATE OUT: June 1ST, 2022

SUBJECT: End Use Product Chemistry Review of "Shenzi SC Insecticide"

FROM: Mohamed Mohamedelhassan *Mohamed Mohamedelhassan* 06-01-2022
Product Chemistry Team
CITAB/RD (7505P)

THROUGH: Shyam Mathur *smathur* 6-01-2022
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CITAB/RD (7505P)

TO: Jasmin Jackson / Venus Eagle, PM 01
I-V Branch 3 / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Shenzi SC Insecticide. In support of the registration application, the registrant has submitted CSF(s) for basic formulation dated September 2, 2021, and the supporting 830 series group A with MRID No. 51623501 & 51623516 (EAM) and group B product chemistry data with MRID No's: 51623507 to -13 & -15. The registrant has claimed similarity to a registered product with Reg. No. 279-9607. CITAB Has been asked to determine the acceptability of the proposed basic CSF, the supporting group A & B product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

Product ingredient source information may be entitled to confidential treatment

Name of Active Ingredient(s): Chlorantraniliprole Technical (95.3%)

PC CODE	Active Ingredient(% purity)	Reg. No.(source of AI)	NC of AI in product

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No: 279-9606, 279-9612, and 279-9607 (only one single registered product can be cited)

3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No

4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [X] Yes; [] No.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 09-02-2021; Re-submitted - Dated: 5-05-2022

☐ Alternate CSFs – ; Re-submitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)?

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☒ No; ☐ NA

Methanol at > 4%: ☐ Yes; ☒ No; ☐ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☒ No; ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Note: Incompatibility to oxidizing agents warning required on the product label

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☒ No; ☐ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	51623501
830.1600	Description of materials used to produce the product		X		A	51623501
830.1650	Description of formulation process		X		A	51623501
830.1670	Discussion on the formation of impurities		X		A	51623501
830.1700	Preliminary analysis				NA	X
830.1750	Certified limits (158.350)	Standard certified limits			A	51623501
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	51623516 AI was determined by RHPLC (UV-VIS, 270 nm) on C-18 column with external standard calibration. Method was validated for specificity, linearity, precision and accuracy

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

RHPLC operating parameters

Instrument : HPLC (LC 2010 CHT shimadzu, LC Solution software)
Column : C-18 (150 mm x 4.6 mm (i.d.); 3.0 µm particle size)
Detector : UV
Wavelength : 270 nm
Injection Volume : 5.0 µL
Flow Rate : 1.0 mL/minute
Column Temperature : 40 °C
Mobile Phase : Solvent A : Buffred Milli-Q Water : Solvent B: Acetonitrile

Time (minute)	Solvent A (%)	Solvent B (%)
0.01	60	40
10	40	60
10.1	5	95
15	5	95
15.1	60	40
20	60	40

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8. Group B:

Self-certified (SC) by applicant– [] Yes; [] No [X] NA

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. / Or Self-certification Dated:
830.6303	Physical State	Off-white liquid	A	51623508
830.6314	Oxidation/Reduction	Compatible with water, kerosene, mono-ammonium phosphate, and zinc dust. Incompatible with potassium permanganate.	A	51623511
830.6315	Flammability	Flash point is greater than 97 °C. It was observed after 97 °C, there was no rise in the temperature of the sample inside the sample-cup as the test item was a water-based formulation. This is due to "Latent Heat of Vaporization".	A	51623515
830.6316	Explosibility	Non-explosive as there was an exothermic decomposition observed up to 430 °C, the decomposition energy was less than 500 J/g.	A	51623510
830.7000	pH	pH for 3 batches (1- and 2-minute split) Batch 1 – 6.29 +- 0.09 and 6.27 +- .06 Batch 2 – 6.40 +- 0.05 and 6.40 +- .01 Batch 3 – 6.52 +- 0.01 and 6.52 +- .01	A	51623512
830.7100	Viscosity	At 20 +- .2 °C = 205.80 cP (mPa s) at 100 rpm At 40 +- .2 °C = 175.1 cP (mPa s) at 100 rpm	A	51623513
830.7300	Density (units)	3 batches Batch 1 – 1.1726 +- 0.0042 Batch 2 – 1.1687 +- 0.0019 Batch 3 – 1.1641 +- 0.0035	A	51623509
830.6317	Storage stability* Or Accelerated storage stability*	No significant change in the physical or chemical property, appearance of the product after storage of 14 days.	A	51623507
830.6320	Corrosion characteristics* or Accelerated corrosion characteristics*	Non-corrosive to the HDPE bottle while storage with respect to the parameters tested.	A	51623507

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*Fluorinated containers used during storage stability & corrosion characteristics studies: [] Yes; [] No; [X] NA

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No: 279-9607; 35% AI on the label) from a product chemistry viewpoint

- ☐ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☐ Not applicable
- ☒ Not determined – Non availability of the accepted basic CSF for cited product

B. Confidential Statement of formula

1. Revised Basic CSF (dated: 05-05-2022)
 - ☒ Acceptable
 - ☐ Not Acceptable
 - ☐ Not Applicable

If not acceptable provide the reasons

2. Alternate CSF(s) #1 (dated:)
 - ☐ Acceptable
 - ☐ Not Acceptable
 - ☒ Not Applicable

If not acceptable give reasons

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable:
- ☐ Acceptable with the exception of Guideline(s):
- ☐ Not required
- ☐ Data cited; ☐ Acceptable; ☐ Not Acceptable

D. Group B Product chemistry data –

Self-certified by applicant (dated) : ☐ Yes; ☒ No

- ☒ Acceptable
- ☐ Not acceptable:
- ☐ Acceptable with the exception of Guideline(s):
- ☐ Not required
- ☐ Data cited ; ☒ Acceptable; ☐ Not Acceptable;
- ☐ Waiver requests; ☐ Acceptable; ☐ Not Acceptable (give reasons)

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E. Product Label/Draft Label

Recommendations – Yes [x]; No []; If yes, give recommendations below:

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

“Do not mix or allow coming in contact with Oxidizing agents. Hazardous Chemical reaction may occur”

Superseded by revision
attached below

Confidential Statement of Formula may be entitled to confidential treatment

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